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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,888	05/31/2005	Thomas R. Young	63-000210US	1367

22798 7590 05/16/2008  
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.  
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EXAMINER
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KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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05/16/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/536,888	<b>Applicant(s)</b> YOUNG ET AL.	
	<b>Examiner</b> RUSSELL KALLIS	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-9,14-16,31-33,39,43,48,66,69,70,77,85 and 97-106 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,9,14-16,31-33,39,43,48,66,69,70,77,85 and 97-106 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/07;7/07;9/07;10/07</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-2, 7, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of increasing carotenoid accumulation in a pineapple plant using sense, antisense, dsRNA, of a heterologous or homologous carotenoid biosynthetic polynucleotide; and plants and plant cells thereof.

Group II, claim(s) 1-2, 7, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of increasing carotenoid accumulation in a pineapple plant using transcription factors; and plants and plant cells thereof.

Group III, claim(s) 1-2, 7, 9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of increasing carotenoid accumulation in a pineapple plant using promoters/enhancers that homologously recombine; and plants and plant cells thereof.

Group IV, claim(s) 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of decreasing carotenoid accumulation in a pineapple plant using sense, antisense or dsRNA of heterologous or homologous carotenoid biosynthetic polynucleotide; and plants and plant cells thereof.

Group V, claim(s) 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of decreasing carotenoid accumulation in a pineapple plant and plants using transcription factors; and plants and plant cells thereof.

Group VI, claim(s) 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to a method of decreasing carotenoid accumulation in a pineapple plant using promoters/enhancers that homologously recombine; and plants and plant cells thereof.

Art Unit: 1638

The inventions listed as Groups I to VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I to VI are drawn to methods of either increasing, (Groups I, II and III) or decreasing, (Groups IV, V, and VI) carotenoid content in a pineapple plant using either sense, antisense or dsRNA of heterologous or homologous carotenoid biosynthetic polynucleotides, Groups I and IV, using transcription factors, Groups II and V, or using promoters/enhancers that homologously recombines, Groups III or VI. Further, the methods of Groups I thru IV differ from each other because they have different starting materials that have different structural features and properties, and have different end products. Moreover, there is no special technical feature linking Groups I thru VI because the technical feature, a carotenoid biosynthetic polypeptide expression regulator, is taught in the art. Firoozabady et al. (U.S. Patent 5,952,543) teach *etr*-related genes in transformed Pineapple (Claims 1 and 6); wherein one of ordinary skill would appreciate that *etr*-related genes are genes that control ethylene production and response during fruit maturation; and thus control carotenoid accumulation in pineapple. Furthermore, Applicant is also required to select from the following 9 polynucleotide segments at least one nucleic acid segment;

- i an isopentenyl diphosphate isomerase
- ii a geranylgeranyl pyrophosphate synthase
- iii a phytoene synthase
- iv a phytoene desaturase
- v a gamma carotene desaturase
- vi a lycopene beta cyclase
- vii a lycopene epsilon cyclase
- viii a beta carotene hydroxylase
- ix an epsilon hydroxylase.

During a telephone conversation with Jonathan Quine on 5/09/2008 a provisional election was made with traverse to prosecute the invention of Group 4, claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106, drawn to drawn to a method of decreasing carotenoid accumulation in a pineapple plant using sense, antisense or dsRNA of heterologous or

Art Unit: 1638

homologous carotenoid biosynthetic polynucleotide of at least one of (iii) a phytoene synthase and (vi) a lycopene beta cyclase.

Affirmation of this election must be made by applicant in replying to this Office action. Claims are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-2, 7-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 are pending. Claim 7 is withdrawn. Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 are examined.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants broadly claims a method of controlling carotenoid accumulation in at least one pineapple cell comprising introducing into a pineapple cell a nucleic acid segment encoding at least one carotenoid biosynthetic polypeptide; whereby the nucleic acid segment is sense, antisense, or dsRNA and corresponds to the endogenous pineapple gene, and either heterologous or homologous to the endogenous pineapple gene and wherein the polypeptide is a phytoene synthase or lycopene beta cyclase carotenoid biosynthetic polypeptide and carotenoid accumulation is decreased; and plant cells and plants thereof.

Applicants present references that describe phytoene synthase and lycopene beta cyclases genes from plants other than pineapple and bacteria on pages 21-22 and 24 of the specification.

Applicant does not describe any nucleic acid segments that are homologous to or correspond to the endogenous polynucleotide encoding phytoene synthase or lycopene beta cyclase in pineapple.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. The court stated that, “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus.” *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of nucleic acid segments that are homologous to or correspond to the endogenous polynucleotide encoding phytoene synthase or lycopene beta cyclase in pineapple. Applicants only describe phytoene synthase and lycopene

Art Unit: 1638

beta cyclases genes from plants other than pineapple and bacteria. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of nucleic acid segments that are homologous to or correspond to the endogenous polynucleotide encoding phytoene synthase or lycopene beta cyclase in pineapple. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for nucleic acid segments that are homologous to or correspond to the endogenous polynucleotide encoding phytoene synthase or lycopene beta cyclase in pineapple, it remains unclear what features identify phytoene synthase or lycopene beta cyclase in pineapple. Since the genus of homologous nucleic acid segments has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior

Art Unit: 1638

art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

Applicants broadly claims a method of controlling carotenoid accumulation in at least one pineapple cell comprising introducing into a pineapple cell a nucleic acid segment encoding at least one carotenoid biosynthetic polypeptide; whereby the nucleic acid segment is sense, antisense, or dsRNA and corresponds to the endogenous pineapple gene, and either heterologous or homologous to the endogenous pineapple gene and wherein the polypeptide is a phytoene synthase or lycopene beta cyclase carotenoid biosynthetic polypeptide and carotenoid accumulation is decreased; and plant cells and plants thereof.

Applicants teach methods of transforming pineapple using polynucleotides encoding carotenoid biosynthetic polypeptides that are heterologous to endogenous pineapple.

Applicants do not teach polynucleotides that are homologous to the endogenous pineapple carotenoid biosynthetic genes; plants thereof or methods thereby.

The state of the art for transformation with phytoene synthase using antisense is unpredictable using heterologous antisense transformation even within a species. For example, tomato transformed with the PSY1 gene encoding an isoform of the tomato phytoene synthase when expressed constitutively using the CaMV promoter had not effect upon the PSY2 isoform of the gene which is expressed primarily in non flowering tissue (Bird C. *et al.* Bio/Technology, July 1991 Vol. 9, No. 7, pp. 635-639; see page 636 in column 1 1<sup>st</sup> paragraph of Results section). This is made evident in the amount of carotenoids that were produced in the various plant tissues. In fruits and flowers where the PSY1 isoform is expressed there was significant reduction in the amount of various carotenoids when compared to non-transformed plants. In

Art Unit: 1638

tissues where PSY2 is expressed, such as leaves, there was no effect upon the level of carotenoids when compared to non-transformed plants (Bramley P. *et al.* The Plant Journal; 1992, Vol. 2 No. 3, pp. 343-349; see Table 4 for comparison of Flower and leaf). Further, the sequence identity relationship between the two isoforms shows that there is 85% sequence conservation at the polynucleotide level in the coding regions between PSY1 and PSY2 (Bartley *et al.* The Journal of Biological Chemistry; 5 December 1993, Vol. 268. No. 34 pp. 25718-25721; see page 25721 in column 1 lines 11-14) and thus the specification does not teach the endogenous sequences and the heterologous sequences taught in the art would not yield a reduction of carotenoid.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 1638

Claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97, 98, 101 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Firoozabady et al. (U.S. Patent 5,952,543) issued September 19, 1999.

Firoozabady teaches *etr*-related genes in transformed Pineapple (Claims 1 and 6); wherein it is recognized in the art that *etr*-related genes are genes broadly encompassing transcription factor and receptor genes that control ethylene production and response during fruit maturation; thereby controlling (either increasing or decreasing) carotenoid accumulation in pineapple; and thus the reference reads upon all the limitations of claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97, 98, 101 and 104.

Claims 1, 9, 39, 43, 66, 69, 77, 97, 98, 101 and 104 are rejected under 35 U.S.C. 102(e) as being anticipated by PP12,861 having a priority dated of July 15, 1999.

PP12,861 teaches in column 6 increased flesh and shell carotenoids (all trans beta-carotene) in Pineapple variety RL41, when compared to parent Smooth Cayenne 'HA 10'; wherein the introduction of the carotenoid biosynthetic polypeptide expression regulator is accomplished by crossing two pineapple varieties (Smooth Cayenne 'HA 10' x Manzanilla 'CO 24'); and thus the reference teaches all the limitations of claims 1, 9, 39, 43, 66, 69, 77, 97, 98, 101 and 104.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Art Unit: 1638

*Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 17, 18, 21-23 of copending Application No. 10/536,885. Although the conflicting claims are not identical, they are not patentably distinct from each other because both pending claim sets are drawn to transformation of non-apical meristematic cells pineapple with carotenoid biosynthetic genes that are obvious over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97, 98, 101 and 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,952,543. Although the conflicting claims are not identical, they are not patentably distinct from each other because the transformation of pineapple using embryogenic callus and the broadly claimed *etr*-like genes is obvious over the broad instant claims drawn to carotenoid biosynthetic polypeptide expression regulator that controls accumulation of carotenoids in pineapple.

Claims 1-2, 8-9, 14-16, 31-33, 39, 43, 48, 66, 69-70, 77, 85, and 97-106 are rejected.

Art Unit: 1638

Claims 14-16, 31-33, 48, 85, 99-100, 102-103 and 105-106 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method of transforming pineapple using organogenetically cultured cells and polynucleotides encoding carotenoid biosynthetic polypeptides to decrease accumulation of carotenoids.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/  
Primary Examiner, Art Unit 1638  
5/06/2008